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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/037,460	03/10/98	HASTINGS G	325800-626(P

022195
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HM12/0614

EXAMINER	
SAOUD, C	
ART UNIT	**PAPER NUMBER**
1646	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/037,460	Applicant(s) HASTINGS et al.
	Examiner Christine Saoud	Group Art Unit 1646

☒ Responsive to communication(s) filed on *Apr 13, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *53-114* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *53-114* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. The original restriction requirement was made against claims 21-52, which were directed to two groups, proteins and methods of use. Applicant has canceled claims 21-52 and submitted new claims 53-114 which correspond to a single inventive group which is different from the previous two inventive groups, which is directed to polynucleotides, vectors, host cells, and methods of making a protein from said polynucleotide. This is considered proper because only a single inventive group is now being claimed. Therefore, Applicant's response of submitting new claims is considered an election by original presentation of polynucleotides, vectors, host cells, and recombinant methods of use. An examination of these claims follows.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

3. Claim 54, 62, 69, 95, and 102 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test"

for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the basic claim. In the instant case, the nucleic acid which is complementary could be infringed without infringing the claim from which it depends, i.e. the nucleic acid which encodes a protein. Therefore, they are improperly dependent and should be rewritten in independent form.

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. Claims 53, 60, and 75 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 9, 14 and 20, respectively of prior U.S. Patent No. 5,747,280. This is a double patenting rejection.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 54-59, 61-67 and 76-80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-10, 14-15, and 20-21, respectively of U.S. Patent No. 5,747,280. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to complementary polynucleotides, vectors, host cells, and methods of use of the polynucleotides of '280. The complementary polynucleotide is obvious over claim 9, 14 or 20 because the structure of DNA is such that if one knows one strand of DNA, the complementary strand is merely the opposing nucleic acid wherein A pairs with T, and G pairs with C. Claims 10, 15, and 21 of '280 are directed to a method of producing a polypeptide using a polynucleotide identical to the one used in the instant claims. In order to make the polypeptide, the use of a vector, host cell, polynucleotide fused to a heterologous polynucleotide and composition of polynucleotide would have been prima facie obvious because the use of such are well-known in the art of recombinant protein production, absent evidence to the contrary. Therefore, the a grant of patent on the instant claims would have the effect of prolonging Applicant's term of exclusivity for embodiments which are obvious in view of the claims of '280.

8. Claims 81-92 are rejected under the judicially created doctrine of double patenting over claims 20-21 of U. S. Patent No. 5,747,280 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: polynucleotides encoding the polypeptide encoded by the cDNA contained in ATCC Deposit No. 75874. Claim 20 of '280 is directed to a polynucleotide which comprises DNA identical to the coding portion of the cDNA in ATCC Deposit No. 75874 which encodes a mature polypeptide. Although the claim does not explicitly claim the polynucleotide encoding the proprotein portion or complete amino acid sequence portion, these regions would also be encompassed by the cDNA contained within ATCC Deposit No. 75874. Therefore, the use of such a polynucleotide in making a polypeptide, including vectors, host cells, and polynucleotides fused to heterologous molecules would also be obvious because these are well-known procedures for making recombinant proteins, absent evidence to the contrary.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

9. Claims 93-114 are rejected under the judicially created doctrine of double patenting over claims 1-22 of U. S. Patent No. 5,747,280 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the instant claims are generic to the claims of '280 or directed to embodiments which would have been obvious over the claims of '280 in light of the knowledge of the prior art at the time of the instant invention. For example, claim 93 is directed to a polynucleotide which encodes at least 30 contiguous amino acids of SEQ ID NO:2. The claims of '280 are directed to polynucleotides which encode SEQ ID NO:2, it was well-known in the prior art at the time of the instant invention that polynucleotides could be used as probes or for encoding antigenic fragments of polypeptides, therefore, claims to polynucleotides which encode something smaller than the entire SEQ ID NO:2 would have been prima facie obvious (including those elements necessary for reproduction of the polynucleotide or polypeptide encoded, including vectors, host cells, heterologous sequences fused to the polynucleotide, etc.).

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

10. Claims 93-100, 108 and 111-112 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 08/196,362 (SEQ ID NO:7788 and 7775), 08/346,731 (SEQ ID NO:552), 08/420,856 (SEQ ID NO:552), 08/221,623 (SEQ ID NO:114), and 08/276,163 (SEQ ID NO:15161). Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass common subject matter of contiguous nucleotides of SEQ ID NO:1 of the instant application. Therefore, the instant claims directed to polynucleotides encoding 30 or 50 contiguous amino acids or encoding an antigenic fragment or hybridizing under the recited hybridization conditions would be encompassed by the polynucleotides of the above mentioned applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 68-92, 101-108 and 11-112 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention appears to employ novel vectors and/or microorganisms. Since the microorganism is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmids' sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 USC § 112 may be satisfied by a deposit of the plasmid and/or microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the DNA sequences and/or microorganism are readily available to the public. Accordingly, it is deemed that a deposit of these plasmids and/or microorganisms should have been made in accordance with 37 C.F.R. 1.801-1.809.

It is noted that applicants have deposited the organism but there is not indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

Claims 68-74 are directed to a polynucleotide encoding a polypeptide comprising amino acids -23 to 163 of SEQ ID NO:2. However, SEQ ID NO:2 only comprises amino acids -21 to 163. Therefore, a claim to this polynucleotide, as well claims to vectors containing, host cells, and methods of use, are not described in the specification as filed, and are considered new matter.

Claim 101 is directed to a cDNA contained in "ATCC Deposit No. 1", however, the instant specification does not provide a basis for "ATCC Deposit No. 1" or describe what would be contained therein. It may be that this is a typographical error, but at the moment, it is also new matter. Correction is required.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 101 and 108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 101 is directed to a "polynucleotide comprising ... a polypeptide fragment encoded by a cDNA" (this is the alternative embodiment of the claim). However, a polynucleotide cannot comprise a polypeptide, rather it encodes a polypeptide. This is also the case for claim 108, part (c).

Claim 108, part (d) is confusing because a nucleic acid sequence will not hybridize because the "sequence" is not the molecule. A "sequence" is merely a characteristic of a nucleic acid molecule, and it is the actual molecule that will be hybridizing.

Claim Rejections - 35 USC § 102

15. Claims 93-100, 108 and 111-112 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 08/196,362 (SEQ ID NO:7788 and 7775), 08/346,731 (SEQ ID NO:552), 08/420,856 (SEQ ID NO:552), 08/221,623 (SEQ ID NO:114), and 08/276,163 (SEQ ID NO:15161) which have a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future patenting of the copending application.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Conclusion

16. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 11, 1999

CHRISTINE SAOUD
PATENT EXAMINER

Christine Saoud